

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CALCULATION OF VOLUME-
WEIGHTED AVERAGE SALES
PRICE FOR MEDICARE PART B
PRESCRIPTION DRUGS**



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EXECUTIVE SUMMARY

OBJECTIVE

To review the Centers for Medicare & Medicaid Services' (CMS) methodology for calculating volume-weighted average sales price (ASP) for Medicare Part B prescription drugs.

BACKGROUND

In January 2005, Medicare began paying for most Part B drugs using an entirely new pricing methodology based on ASPs. Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, the product dosage form, and the package size of a drug. Manufacturers must provide CMS with the ASP and sales volume for each of their NDCs on a quarterly basis.

Although manufacturers submit ASP data by NDCs, CMS does not reimburse Medicare providers for drugs using NDCs. Instead, CMS uses procedure codes. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. Given that Medicare reimbursement for Part B drugs is based on HCPCS codes rather than NDCs, and that more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. The NDC-level information in this crosswalk can then be used to calculate an ASP for each covered HCPCS code.

When CMS calculates payment amounts for HCPCS codes, it must weight ASPs at the NDC level by the amount of the drug sold during the quarter. Pursuant to section 1847A(b)(1) of the Social Security Act (the Act), the Medicare allowance for most Part B drug codes is then equal to 106 percent of the volume-weighted ASPs for those HCPCS codes. Section 1847A(b)(3) of the Act specifies the way to calculate a volume-weighted ASP based on information reported by manufacturers, and this calculation assumes that the unit of ASP submission is the lowest identifiable quantity of the drug (e.g., 1 milliliter, 1 tablet). However, the Act also granted the Secretary of the Department of Health and Human Services (Secretary) discretion to establish a different unit for reporting ASPs.¹ Acting on behalf of the Secretary, CMS opted to exercise this discretion and changed the unit of ASP submission to the

¹ Social Security Act § 1847A(b)(2)(B).

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amount of the drug represented by the NDC.² The amount of the drug represented by one NDC may differ from the amount of the drug represented by another NDC. It may also differ from the amount of the drug specified by the HCPCS code. Therefore, collecting ASPs and sales volume by NDC means that there is no longer a standard unit across NDCs to use in calculating a volume-weighted ASP for the HCPCS code. To standardize the amount of the drug contained in each of the NDCs associated with a given HCPCS code, CMS introduced billing units into the calculation of volume-weighted ASPs. The number of billing units in an NDC describes the number of HCPCS code units in that NDC.

For this study, we obtained volume-weighted ASPs for the first quarter of 2005, which CMS calculated based on data submitted by manufacturers for the third quarter of 2004. We reviewed CMS's calculations of volume-weighted ASPs for 459 HCPCS codes. We also developed an alternate method for calculating volume-weighted ASP and used this alternate method to calculate volume-weighted ASPs and reimbursement amounts for each of the 459 HCPCS codes. We then compared reimbursement amounts calculated using the alternate method to those calculated by CMS and identified codes for which the reimbursements differed. We also estimated the monetary impact of using the Office of Inspector General (OIG) reimbursement methodology rather than the CMS reimbursement methodology.

FINDINGS

The method CMS uses to calculate volume-weighted average sales price is incorrect. We believe that the method CMS uses to calculate a volume-weighted ASP for a HCPCS code is mathematically incorrect because CMS does not use billing units consistently throughout its equation. Although CMS uses billing units to standardize ASPs across NDCs for each HCPCS code, it does not similarly standardize sales volume across NDCs. As a result, CMS's equation may not always yield a volume-weighted ASP that is consistent with the volume-weighted ASP derived from the calculation set forth in the law. Recognizing this inconsistency, OIG developed an alternate method for calculating the volume-weighted ASP, which produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the calculation set forth in the ASP legislation. To illustrate this point, we calculated the volume-weighted

²42 C.F.R. § 414.802 (2004).

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ASP for a HCPCS code using the calculation derived from section 1847A(b)(3) of the Act, CMS's calculation, and OIG's alternate calculation. The calculation derived from the statute and OIG's alternate calculation both yielded the same volume-weighted ASP for the HCPCS code, whereas CMS's calculation yielded a different volume-weighted ASP.

Because CMS calculates volume-weighted ASPs incorrectly, current and future reimbursement amounts may not be accurate. According to our analysis of prices published in the first quarter of 2005, 46 percent of HCPCS codes had a reimbursement amount that was higher than it should have been, resulting in an estimated \$115 million loss to Medicare in 2005. For 13 percent of HCPCS codes, CMS's reimbursement amount was lower than it should have been, representing an estimated \$5 million loss to providers in 2005. For the remaining 41 percent of HCPCS codes, there was no difference between the reimbursement amount calculated by CMS and the reimbursement amount calculated by OIG. In addition, CMS's incorrect calculation affects adjustments to drug reimbursement amounts based on OIG pricing comparisons mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

RECOMMENDATION

Volume-weighted ASPs form the basis on which providers are reimbursed for most Part B drugs. Therefore, any inaccuracies in these amounts have significant implications for the Medicare program, its health care providers, and its beneficiaries. We believe that CMS's method for calculating volume-weighted ASPs is incorrect, and that the incorrect calculation can produce improper reimbursement amounts. Although we identified many HCPCS codes for which reimbursement was too high in the first quarter of 2005, we also found a number of HCPCS codes for which reimbursement was too low. Moreover, the ratio between codes with reimbursements that are too high and those with reimbursements that are too low may periodically fluctuate given that ASP data change from quarter to quarter.

Furthermore, CMS's incorrect calculation has implications for future adjustments to reimbursement amounts based on OIG pricing comparisons mandated by the MMA. It is therefore critical that the calculation of volume-weighted ASPs be performed correctly for all HCPCS codes.

EXECUTIVE SUMMARY

CMS should change its method for calculating volume-weighted ASPs.

We propose that CMS adopt an alternate equation, which uses billing units consistently and produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the calculation set forth in section 1847A(b)(3) of the Act.

AGENCY COMMENTS

CMS indicated that it will consider the report's findings in its ongoing efforts to enhance implementation of the new ASP payment methodology. CMS also stated that it presented the current ASP calculation in proposed rule 70 Fed. Reg. 45764, 45844 (August 8, 2005) and received public comments on its approach. As CMS gains more experience with the ASP data, and as more information becomes available, CMS stated that it may consider altering the ASP methodology.

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to believe that CMS is calculating volume-weighted ASP incorrectly, and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth in section 1847A(b)(3) of the Act. According to our analysis of prices from the first quarter of 2005, the net effect of inaccurate payments was a loss for the Medicare Trust Fund.

OIG's concerns about the ASP calculation were echoed in the comments CMS received on proposed rule 70 Fed. Reg. 45764, 45844 (August 8, 2005). In response to the proposed rule, several manufacturers or their representatives noted that products are available in different package sizes and that a billing code may encompass multiple NDCs; therefore, weighting the ASP payment amount by NDCs sold does not reflect the true weighted average price per billing unit. These commenters suggested that CMS revise its calculation so that the payment limit is based on the weighted ASP of the number of billing units sold rather than the number of NDCs sold. Commenters on the proposed rule recognized that such a change could result in an increase or decrease to the reimbursement amount, but recommended that the calculation be altered nonetheless.

We look forward to receiving CMS's comments on this final report.

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► I N T R O D U C T I O N

OBJECTIVE

To review the Centers for Medicare & Medicaid Services' (CMS) methodology for calculating volume-weighted average sales price (ASP) for Medicare Part B prescription drugs.

BACKGROUND

Medicare Coverage of Prescription Drugs

Medicare Part B currently covers a limited number of outpatient prescription drugs. Those that are covered include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines. With the advent of the Part D benefit in 2006, Medicare will offer beneficiaries additional insurance coverage for certain outpatient prescription drugs that are not covered under Part B.

Use of Average Sales Price in the Medicare Program

In January 2005, Medicare began paying for most Part B drugs using an entirely new pricing methodology based on ASPs.¹ Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.²

¹Prior to 2005, the pricing methodology for most Part B drugs was based on the average wholesale price (AWP). For 2004, the reimbursement amount for most covered drugs was based on 85 percent of the AWP as published in national pricing compendia such as the "Red Book." Prior to 2004, Medicare Part B reimbursed for covered drugs based on the lower of either the billed amount or 95 percent of AWP.

²Pursuant to section 1927 (c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

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Manufacturers' Reporting of Average Sales Price Data

Pursuant to section 1927(b)(3)(A)(iii) of the Act, manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, the product dosage form, and the package size of a drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of the quarter.

Section 1847A(b)(2)(B) of the Act defines the unit of ASP submission as the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological. Accordingly, manufacturers would submit, with respect to each NDC, the ASP and volume of sales for the smallest amount of the drug contained in the NDC—e.g., manufacturers would submit an ASP for 1 milliliter and the number of 1-milliliter units sold. However, section 1847A(b)(2)(B) of the Act also grants the Secretary of the Department of Health and Human Services (Secretary) discretion to establish a different unit for reporting ASPs for years after 2004. Acting on behalf of the Secretary, CMS opted to exercise this discretion and changed the unit of ASP submission from the lowest identifiable quantity of the drug (e.g., 1 milliliter, 1 tablet) to the amount of the drug represented by the NDC (e.g., 50 milliliters, 100 tablets).³ Therefore, manufacturers currently report an ASP for the amount of the drug in the NDC rather than for the smallest identifiable quantity of the drug.

Use of Healthcare Common Procedure Coding System Codes

Although manufacturers submit ASP data by NDCs, CMS does not reimburse Medicare providers for drugs using NDCs. Instead, CMS uses procedure codes. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. Each HCPCS code for drugs defines the drug name and dosage size but does not specify manufacturer information or package size data.

Given that Medicare reimbursement for Part B drugs is based on HCPCS codes rather than NDCs, and that more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that “crosswalks” manufacturers’ NDCs to HCPCS codes. The NDC-level information in this crosswalk can then be used to calculate an ASP for each covered HCPCS code. Under the ASP pricing methodology, the

³42 C.F.R. § 414.802 (2004).

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Medicare allowance for most Part B drugs is equal to 106 percent of the ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

Calculation of Volume-Weighted ASP

Calculation of a Volume-Weighted ASP Based on the Methodology Set Forth in the Law. As mentioned above, manufacturers submit ASPs by NDCs, and more than one NDC may meet the definition of a HCPCS code. These multiple NDCs are then used to calculate an ASP for the HCPCS code. However, each NDC does not contribute equally toward the payment amount for a HCPCS code. Consistent with section 1847A(b)(3) of the Act, when payment amounts for HCPCS codes are calculated, ASPs at the NDC level must be weighted by the amount of the drug sold during the quarter. This means that the ASP for a drug with a high volume of sales will have greater influence on the reimbursement amount for a HCPCS code than an ASP for a drug with a low volume of sales. Section 1847A(b)(3) of the Act describes the following equation for calculating volume-weighted ASP:

$$\text{Volume-Weighted ASP for One Unit} = \frac{\text{Sum of (ASP for One Unit * Number of Units Sold)}}{\text{Sum of Number of Units Sold}}$$

This equation assumes that the unit of ASP submission, as defined in section 1847A(b)(2)(B) of the Act, is the lowest identifiable amount of the drug. Therefore, the equation yields a volume-weighted ASP for the lowest identifiable amount of the drug—e.g., a volume-weighted ASP for 1 milliliter or 1 tablet. This amount can then be multiplied by the amount of the drug specified by the HCPCS code, which results in the volume-weighted ASP for the HCPCS code.⁴ For example, if a HCPCS code represents 5 milliliters of a drug, and the volume-weighted ASP for 1 milliliter of the drug as determined by the calculation in the law is \$2, then the volume-weighted ASP for the HCPCS code would be 5 times \$2, or \$10.

Calculation of a Volume-Weighted ASP According to CMS. The calculation specified in the statute uses the lowest identifiable amount of the drug as the standard unit of the drug across NDCs. However, because CMS exercised its discretion and changed the unit of ASP submission from

⁴The statute does not specifically address converting the volume-weighted ASP for the lowest identifiable amount of the drug to a reimbursement amount for the HCPCS code. However, the conversion can be achieved by multiplying the volume-weighted ASP for one unit by the amount of the drug specified by the HCPCS code.

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the lowest identifiable amount of the drug to the entire amount of the drug represented by the NDC, the calculation described in the law could not be applied exactly as written.⁵ The entire amount of the drug contained in an NDC may differ from one NDC to the next. It may also differ from the amount of the drug specified by the HCPCS code. Therefore, collecting ASPs and sales volume by NDCs means that there is no longer a standard unit across NDCs to use in calculating a volume-weighted ASP for the HCPCS code. It was therefore necessary for CMS to modify the method for calculating a volume-weighted ASP described in the law.

To standardize the amount of the drug contained in each of the NDCs associated with a given HCPCS code, CMS introduced billing units into the calculation of a volume-weighted ASP. The number of billing units in an NDC, which CMS calculates as part of its crosswalk files, describes the number of HCPCS code units that are in that NDC. For instance, an NDC may contain a total of 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. The equation that CMS uses to calculate a volume-weighted ASP is as follows:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC} * \text{Number of NDCs Sold}}{\text{Billing Units in NDC}} \right]}{\text{Sum of Number of NDCs Sold}}$$

METHODOLOGY

We obtained CMS's volume-weighted ASPs for the first quarter of 2005, which were calculated based on NDC-level data submitted by manufacturers for the third quarter of 2004. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes. Both the volume-weighted ASPs and the crosswalk file were updated as of January 13, 2005.

As of January 13, 2005, CMS had established prices for 459 HCPCS codes based on the ASP reimbursement methodology. This total excludes HCPCS code J3490, which is defined as "unclassified drugs." Reimbursement amounts for the 459 HCPCS codes were based on ASP data for 2,399 NDCs. We reviewed the method CMS used to calculate a volume-weighted ASP for each of the 459 HCPCS codes, examining each

⁵Discretion to change the unit of ASP submission is permitted by section 1847A(b)(2)(B) of the Act.

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step to ensure that CMS's calculation was mathematically correct. However, we did not verify the accuracy of the billing unit information contained in CMS's crosswalk file.

We concluded that CMS's calculation was problematic, and therefore developed an alternate method for calculating a volume-weighted ASP and used this method to calculate alternate volume-weighted ASPs for each of the 459 HCPCS codes. Under this method, billing units are used as the standard unit across all NDCs for a particular HCPCS code, just as they are in CMS's calculation. However, the Office of Inspector General's (OIG) calculation uses billing units differently than CMS's calculation. OIG's alternate equation is as follows:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of (ASP for NDC * Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}}$$

As mentioned earlier, the Medicare allowance for a HCPCS code is equal to 106 percent of the volume-weighted ASP. Therefore, to determine what the Medicare reimbursement amount would be according to the alternate calculation, we multiplied OIG's volume-weighted ASPs for each of the 459 codes by 1.06. We then compared our reimbursement amounts to CMS's reimbursement amounts and identified codes for which the reimbursements differed. To estimate the monetary impact of using the OIG reimbursement rather than the CMS reimbursement, we first subtracted OIG's first quarter 2005 reimbursement amount from CMS's first quarter 2005 reimbursement amount for each HCPCS code. We then multiplied the difference by the number of services that were allowed by Medicare for each HCPCS code in 2004, as reported in CMS's Part B Extract and Summary System (BESS).⁶ This estimate assumes that the volume-weighted ASP for each HCPCS code will remain consistent throughout 2005. However, the ASP amounts submitted by manufacturers may actually vary from quarter to quarter.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

⁶At the time of extraction, BESS data were 96 percent complete for HCPCS codes processed by local carriers and 91 percent complete for HCPCS codes processed by the durable medical equipment regional carriers.

FINDINGS

The method CMS uses to calculate volume-weighted average sales price is incorrect

The method CMS uses to calculate a volume-weighted ASP for a HCPCS code is

mathematically incorrect because CMS does not use billing units consistently throughout its equation. Although CMS uses billing units to standardize ASPs across NDCs for each HCPCS code, it does not similarly standardize sales volume across NDCs. As a result, CMS's equation may not always yield the same volume-weighted ASP as that derived from the equation set forth in section 1847A(b)(3) of the Act.⁷

To address this inconsistency, OIG developed an alternate method for calculating a volume-weighted ASP. The alternate calculation corrects the deficiencies in CMS's calculation by multiplying the number of NDCs sold by the number of billing units in the NDC in both the numerator and denominator of the equation. As a result, OIG's alternate calculation produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the ASP calculation set forth in the Act. A more detailed explanation of OIG's equation is presented in Appendix A.

To illustrate this point, we calculated volume-weighted ASP for HCPCS code X using the calculation derived from the statute, CMS's calculation, and OIG's alternate calculation. In this example, there are four different NDCs that meet the description of HCPCS code X, which is defined as 5 milliliters of Drug A. The table on the next page provides ASP information for each of the four NDCs. Columns C and D demonstrate the way that manufacturers would have submitted the ASP data if CMS had used the original unit of ASP submission (i.e., the lowest identifiable quantity of the drug). Columns E and F illustrate the way that manufacturers would currently submit the ASP and sales volume for each of the NDCs (i.e., in terms of NDC units). Column G shows the number of 5-milliliter units that are contained in each of the four NDCs associated with HCPCS code X.

As shown on the next page, CMS's calculation yields a volume-weighted ASP for HCPCS code X that is \$0.73 higher than the volume-weighted ASP derived from either the calculation specified in section 1847A(b)(3) of the Act or OIG's alternate calculation.

⁷The calculation described in section 1847A(b)(3) of the Act does consistently use a standardized unit (i.e., the lowest identifiable quantity of the drug).

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Calculating A Volume-Weighted ASP for HCPCS Code X (5 mL of Drug A)

ASP Information for Four NDCs Associated With HCPCS Code X						
A	B	C	D	E	F	G
NDC	Total Amount of Drug in NDC	ASP for One Unit (1 mL)	Number of 1-mL Units Sold	ASP for Entire NDC	Number of NDCs Sold	Billing Units in NDC
1	2 mL	\$4.35	57,600	\$8.70	28,800	0.4
2	2 mL	\$4.25	84,660	\$8.50	42,330	0.4
3	3 mL	\$3.98	116,640	\$11.94	38,880	0.6
4	4 mL	\$3.14	210,760	\$12.56	52,690	0.8

1. Volume-Weighted ASP for HCPCS Code X Based on the Calculation in the Law

$$\left(\frac{\text{Sum of (ASP for One Unit * Number of Units Sold)}}{\text{Sum of Number of Units Sold}} \right) \cdot \text{Amount of Drug Specified by HCPCS Code} = \text{Volume-Weighted ASP for HCPCS Code}$$

$$\frac{(\$4.35 * 57,600) + (\$4.25 * 84,660) + (\$3.98 * 116,640) + (\$3.14 * 210,760)}{57,600 + 84,660 + 116,640 + 210,760} \cdot 5 \text{ mL} = \boxed{\$18.49}$$

2. Volume-Weighted ASP for HCPCS Code X Based on CMS's Calculation

$$\frac{\text{Sum of} \left(\frac{\text{ASP for NDC}}{\text{Billing Units in NDC}} \cdot \text{Number of NDCs Sold} \right)}{\text{Sum of Number of NDCs Sold}} = \text{Volume-Weighted ASP for HCPCS Code}$$

$$\frac{\left(\frac{\$8.70}{0.4} \cdot 28,800 \right) + \left(\frac{\$8.50}{0.4} \cdot 42,330 \right) + \left(\frac{\$11.94}{0.6} \cdot 38,880 \right) + \left(\frac{\$12.56}{0.8} \cdot 52,690 \right)}{28,800 + 42,330 + 38,880 + 52,690} = \boxed{\$19.22}$$

3. Volume-Weighted ASP for HCPCS Code X Based on OIG's Calculation

$$\frac{\text{Sum of (ASP for NDC * Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}} = \text{Volume-Weighted ASP for HCPCS Code}$$

$$\frac{(\$8.70 * 28,800) + (\$8.50 * 42,330) + (\$11.94 * 38,880) + (\$12.56 * 52,690)}{(28,800 * 0.4) + (42,330 * 0.4) + (38,880 * 0.6) + (52,690 * 0.8)} = \boxed{\$18.49}$$

F I N D I N G S

We believe that the discrepancy between CMS's results and the results of the other two calculations stems from the fact that CMS uses billing units to standardize ASPs but not the number of NDCs sold. In the numerator of its equation, CMS standardizes ASPs across NDCs by calculating an ASP per billing unit for each NDC.⁸ However, CMS does not convert the number of NDCs sold into the number of billing units sold in the numerator, nor does CMS convert NDCs sold into billing units sold in the denominator. Instead, CMS continues to use the number of NDCs sold. CMS treats these sales figures as if they represent a standard amount of the drug when, in fact, the amount of the drug in each NDC may vary from one NDC to the next. Summing the number of NDCs sold across NDCs is similar to concluding that 5 nickels, 2 dimes, and 1 quarter equals 8 cents because $5+2+1=8$.

Because CMS calculates volume-weighted ASPs incorrectly, current and future reimbursement amounts may not be accurate

Volume-weighted ASPs form the basis for the reimbursement of most Part B drugs. Therefore, the incorrect calculation of volume-

weighted ASPs has a significant impact on the Medicare program, its health care providers, and its beneficiaries.

The method CMS uses to calculate volume-weighted ASPs often results in reimbursement amounts that are either too high or too low

According to our analysis of data from the first quarter of 2005, almost 60 percent of published HCPCS codes had a reimbursement amount that was either too high or too low when compared to the results of OIG's alternate calculation. Reimbursement amounts for the remaining HCPCS codes would have been the same regardless of whether CMS's or OIG's calculation was used.

For 46 percent of HCPCS codes, CMS's reimbursement amount was too high.

For 212 of the 459 HCPCS codes, the Medicare reimbursement amount as calculated by CMS was higher than the Medicare reimbursement amount as calculated by OIG. Of these HCPCS codes, 18 had a reimbursement amount that was at least twice as much as it would have been using OIG's method, and 3 had a reimbursement amount that was at least 5 times what it would have been using the OIG method.

⁸The ASP per billing unit is the ASP for the entire NDC divided by the number of billing units in the NDC. In terms of the table on page 7, this would be Column E divided by Column G.

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Based on the number of services allowed in 2004, the Medicare program and its beneficiaries would pay an estimated \$115 million less in 2005 if reimbursement amounts were calculated using OIG's method rather than CMS's method. Adjusting the calculation for just two codes, J9217 and J2275, would result in an estimated savings of almost \$50 million for the Medicare program in the year 2005.⁹ A list of all 212 HCPCS codes is presented in Appendix B.

For 13 percent of HCPCS codes, CMS's reimbursement amount was too low. For 61 of the 459 HCPCS codes, the Medicare reimbursement amount as calculated by CMS was lower than the Medicare reimbursement amount as calculated by OIG. Of these HCPCS codes, seven had a reimbursement amount that was at least 10 percent lower than it would have been using OIG's calculation.

We estimate that providers who bill Medicare for the 61 HCPCS codes would gain about \$5 million in the year 2005 if OIG's method for calculating a volume-weighted ASP were used instead of CMS's method. In fact, providers who bill Medicare for one HCPCS code alone, J2430, would receive an estimated \$1.6 million more in the year 2005.¹⁰ A list of all 61 HCPCS codes is presented in Appendix C.

For the remaining 41 percent of HCPCS codes, there was no difference between the reimbursement amount calculated by CMS and the reimbursement amount calculated by OIG. CMS and OIG calculations yielded the same result for the remaining 186 HCPCS codes. In these cases, CMS's inconsistent use of billing units did not affect the results, usually because there was only one NDC used to price the HCPCS code and therefore no need to weight the data by volume. A list of these 186 HCPCS codes is presented in Appendix D.

CMS's incorrect calculation of volume-weighted ASPs affects statutory mandates to monitor and adjust drug reimbursement amounts

To monitor new reimbursement amounts based on ASPs, section 1847A(d)(2)(B) of the Act mandates that OIG perform comparisons between ASPs and both average manufacturer prices (AMP) and widely available market prices (WAMP). If OIG determines that the ASP for a drug exceeds either the AMP or the WAMP by 5 percent, the Secretary

⁹HCPCS code J9217 represents leuprolide acetate (for depot suspension), 7.5 mg; and HCPCS code J2275 represents an injection of morphine sulfate (preservative-free sterile solution), per 10 mg.

¹⁰HCPCS code J2430 represents an injection of pamidronate disodium, per 30 mg.

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may substitute the payment amount for that drug product with the lower of either the WAMP or 103 percent of the AMP.

CMS's incorrect calculation affects the outcome of future pricing comparisons performed by OIG, which in turn affect whether reimbursement amounts are lowered. If volume-weighted ASPs and volume-weighted AMPs are not calculated correctly, reimbursement amounts for some HCPCS codes may be lowered to 103 percent of the AMP or the WAMP when they should not be, and reimbursement amounts for other codes would remain the same when, according to the statute, they may be lowered.

The following example illustrates a case in which the method used to calculate volume-weighted ASPs and AMPs affects the outcome of the comparison between the ASP and the AMP. In this example, CMS's calculation results in a volume-weighted ASP of \$1.20 and a volume-weighted AMP of \$1.10 for a given HCPCS code, while OIG's calculation results in a volume-weighted ASP of \$1.17 and a volume-weighted AMP of \$1.15 for that same HCPCS code. According to CMS's calculation, the ASP exceeds the AMP by 9 percent, which meets the 5-percent threshold specified in the Act. The reimbursement amount for this drug would then be eligible to be lowered to 103 percent of the AMP, or \$1.13. However, according to OIG's calculation, the ASP exceeds the AMP by only 2 percent, which does not meet the 5-percent threshold. Using OIG's calculation, the reimbursement for this HCPCS code would not be lowered.

► R E C O M M E N D A T I O N

Volume-weighted ASPs form the basis on which providers are reimbursed for most Part B drugs. Therefore, any inaccuracies in these amounts have significant implications for the Medicare program, its health care providers, and its beneficiaries. We believe that CMS's method for calculating volume-weighted ASPs is incorrect, and that the incorrect calculation can produce improper reimbursement amounts. Although we identified many HCPCS codes for which reimbursement was too high in the first quarter of 2005, we also found a number of HCPCS codes for which reimbursement was too low. Moreover, the ratio between codes with reimbursements that are too high and those with reimbursements that are too low may periodically fluctuate given that the ASP data change from quarter to quarter.

Furthermore, CMS's incorrect calculation has implications for future adjustments to reimbursement amounts based on OIG pricing comparisons mandated by the MMA. It is therefore critical that the calculation of volume-weighted ASPs be performed correctly for all HCPCS codes.

CMS Should Change its Method for Calculating Volume-Weighted ASPs

We propose that CMS adopt an alternate equation, which uses billing units consistently and produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the calculation set forth in section 1847A(b)(3) of the Act.

AGENCY COMMENTS

CMS indicated that it will consider the report's findings in its ongoing efforts to enhance implementation of the new ASP payment methodology. CMS also stated that it presented the current ASP calculation in proposed rule 70 Fed. Reg. 45764, 45844 (August 8, 2005) and received public comments on its approach. As CMS gains more experience with the ASP data, and as more information becomes available, CMS stated that it may consider altering the ASP methodology.

The full text of CMS's comments can be found in Appendix E.

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to believe that CMS is calculating volume-weighted ASP incorrectly, and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth in section 1847A(b)(3) of the Act. According to

R E C O M M E N D A T I O N

our analysis of prices from the first quarter of 2005, the net effect of inaccurate payments is a loss for the Medicare Trust Fund.

OIG's concerns about the ASP calculation were echoed in the comments CMS received on proposed rule 70 Fed. Reg. 45764, 45844 (August 8, 2005). In response to the proposed rule, several manufacturers or their representatives noted that products are available in different package sizes and that a billing code may encompass multiple NDCs; therefore, weighting the ASP payment amount by NDCs sold does not reflect the true weighted average price per billing unit. These commenters suggested that CMS revise its calculation so that the payment limit is based on the weighted ASP of the number of billing units sold rather than the number of NDCs sold. Commenters on the proposed rule recognized that such a change could result in an increase or decrease to the reimbursement amount, but recommended that the calculation be altered nonetheless.

We look forward to receiving CMS's comments on this final report.

▶ A P P E N D I X ~ A

1. The Equation Used by CMS to Calculate a Volume-Weighted ASP

In the following equation, a “unit” is defined as the entire amount of the drug contained in the NDC:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC} * \text{Number of NDCs Sold}}{\text{Billing Units in NDC}} \right]}{\text{Sum of Number of NDCs Sold}}$$

2. The Equation Used by OIG to Calculate a Volume-Weighted ASP

We suggest that CMS’s calculation should be modified by multiplying the number of NDCs sold by the number of billing units in the NDC in both the numerator and denominator of the equation:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC} * \text{Number of NDCs Sold} * \text{Billing Units in NDC}}{\text{Billing Units in NDC}} \right]}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}}$$

However, the terms “Billing Units in NDC” in the numerator of the equation cancel each other out:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC} * \text{Number of NDCs Sold} * \cancel{\text{Billing Units in NDC}}}{\cancel{\text{Billing Units in NDC}}} \right]}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}}$$

Therefore, OIG’s equation is written in the following way:

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of (ASP for NDC * Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}}$$

► A P P E N D I X ~ B

**Table 1: Codes for Which CMS's Reimbursement Amount Exceeded
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Gain to Medicare)
J9217	\$253.13	\$230.09	\$23.04	10.01%	\$32,374,264.32
J2275	\$11.75	\$4.88	\$6.87	140.78%	\$16,556,926.71
Q0136	\$10.18	\$10.07	\$0.11	1.09%	\$9,324,462.07
J7317	\$110.27	\$101.03	\$9.24	9.15%	\$5,975,905.32
J9202	\$189.79	\$184.64	\$5.15	2.79%	\$5,013,185.10
J1260	\$6.61	\$5.78	\$0.83	14.36%	\$4,859,645.85
J1563	\$56.72	\$55.57	\$1.15	2.07%	\$4,688,351.05
J2790	\$102.36	\$97.93	\$4.43	4.52%	\$4,108,156.07
J1626	\$7.09	\$6.57	\$0.52	7.91%	\$2,601,538.16
J7644	\$0.29	\$0.28	\$0.01	3.57%	\$2,137,831.40
J1100	\$0.14	\$0.03	\$0.11	366.67%	\$2,038,162.17
J7506	\$0.22	\$0.03	\$0.19	633.33%	\$1,694,987.15
J2353	\$85.39	\$82.91	\$2.48	2.99%	\$1,630,845.52
J3420	\$0.47	\$0.11	\$0.36	327.27%	\$1,465,893.00
J9045	\$125.47	\$124.72	\$0.75	0.60%	\$1,441,580.25
J9390	\$69.09	\$65.55	\$3.54	5.40%	\$1,324,887.48
J1030	\$5.36	\$4.70	\$0.66	14.04%	\$1,324,384.38
J1642	\$0.07	\$0.02	\$0.05	250.00%	\$1,082,555.20
J1040	\$9.75	\$9.20	\$0.55	5.98%	\$982,224.10
J3301	\$1.32	\$1.19	\$0.13	10.92%	\$952,077.49
J1080	\$12.62	\$9.01	\$3.61	40.07%	\$933,574.88
J1170	\$1.71	\$1.39	\$0.32	23.02%	\$825,428.80
J0150	\$31.07	\$27.74	\$3.33	12.00%	\$804,461.40
J7507	\$3.31	\$3.29	\$0.02	0.61%	\$739,314.16
J2270	\$1.86	\$0.56	\$1.30	232.14%	\$691,308.80
J1564	\$0.57	\$0.55	\$0.02	3.64%	\$671,911.78
J1245	\$1.93	\$1.49	\$0.44	29.53%	\$569,168.60
J1325	\$12.16	\$11.91	\$0.25	2.10%	\$523,334.75
J9190	\$1.68	\$1.43	\$0.25	17.48%	\$437,058.50
J2271	\$5.07	\$2.60	\$2.47	95.00%	\$424,229.91
J0880	\$17.72	\$17.71	\$0.01	0.06%	\$408,226.02
J1550	\$100.02	\$94.54	\$5.48	5.80%	\$395,721.76
J0256	\$3.28	\$3.08	\$0.20	6.49%	\$386,787.60
J0475	\$180.49	\$176.03	\$4.46	2.53%	\$382,346.88
J1250	\$5.11	\$3.69	\$1.42	38.48%	\$348,010.76
J0152	\$70.00	\$69.75	\$0.25	0.36%	\$344,831.75
J7608	\$2.30	\$1.73	\$0.57	32.95%	\$299,276.22
J0640	\$1.30	\$1.22	\$0.08	6.56%	\$287,072.72
J2912	\$0.15	\$0.03	\$0.12	400.00%	\$276,065.04
J9000	\$4.25	\$3.92	\$0.33	8.42%	\$265,254.99
J9265	\$15.85	\$15.72	\$0.13	0.83%	\$243,959.95
J0895	\$15.67	\$15.40	\$0.27	1.75%	\$182,897.19

A P P E N D I X ~ B

**Table 1: Codes for Which CMS's Reimbursement Amount Exceeded
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Gain to Medicare)
J2260	\$4.77	\$4.49	\$0.28	6.24%	\$173,673.64
Q0179	\$30.86	\$28.92	\$1.94	6.71%	\$159,836.60
J1885	\$0.64	\$0.50	\$0.14	28.00%	\$158,952.64
J9214	\$13.12	\$13.06	\$0.06	0.46%	\$136,586.58
J7669	\$0.26	\$0.25	\$0.01	4.00%	\$135,115.32
J2997	\$30.15	\$27.10	\$3.05	11.25%	\$125,806.40
J1580	\$1.44	\$0.52	\$0.92	176.92%	\$124,395.04
J3303	\$1.76	\$1.37	\$0.39	28.47%	\$124,372.17
J9260	\$2.16	\$1.53	\$0.63	41.18%	\$109,302.48
Q0187	\$1,043.05	\$1,037.96	\$5.09	0.49%	\$103,820.73
J1745	\$53.08	\$53.07	\$0.01	0.02%	\$93,175.94
J2175	\$1.37	\$0.85	\$0.52	61.18%	\$91,967.72
J1950	\$445.11	\$429.96	\$15.15	3.52%	\$78,295.20
J1644	\$0.10	\$0.04	\$0.06	150.00%	\$75,384.24
J2300	\$1.33	\$0.54	\$0.79	146.30%	\$73,007.85
J2250	\$0.48	\$0.29	\$0.19	65.52%	\$67,366.02
J2820	\$21.67	\$21.59	\$0.08	0.37%	\$58,779.84
J3010	\$0.27	\$0.24	\$0.03	12.50%	\$56,022.66
J9090	\$13.91	\$11.91	\$2.00	16.79%	\$54,766.00
J2355	\$243.35	\$241.67	\$1.68	0.70%	\$46,045.44
J1200	\$0.94	\$0.88	\$0.06	6.82%	\$43,953.60
J3370	\$2.42	\$2.27	\$0.15	6.61%	\$42,812.10
J0280	\$0.50	\$0.35	\$0.15	42.86%	\$41,536.95
J1817	\$2.18	\$2.15	\$0.03	1.40%	\$39,502.35
J3410	\$0.35	\$0.08	\$0.27	337.50%	\$37,937.43
J0698	\$5.02	\$4.32	\$0.70	16.20%	\$37,765.00
J9062	\$18.37	\$17.94	\$0.43	2.40%	\$36,858.31
J7060	\$0.79	\$0.69	\$0.10	14.49%	\$35,240.00
J7051	\$0.01	\$0.00	\$0.01	N/A	\$34,727.40
J1940	\$0.49	\$0.35	\$0.14	40.00%	\$33,559.82
J2010	\$3.48	\$3.33	\$0.15	4.50%	\$31,658.10
J3480	\$0.08	\$0.04	\$0.04	100.00%	\$29,124.64
J9182	\$4.51	\$4.35	\$0.16	3.68%	\$28,641.60
J7070	\$2.73	\$2.22	\$0.51	22.97%	\$28,536.54
J2060	\$1.27	\$0.98	\$0.29	29.59%	\$27,982.97
J9100	\$1.68	\$1.12	\$0.56	50.00%	\$27,009.36
Q0180	\$47.72	\$43.33	\$4.39	10.13%	\$26,620.96
J2150	\$1.02	\$0.75	\$0.27	36.00%	\$26,580.42
J1631	\$5.80	\$5.49	\$0.31	5.65%	\$26,469.35
J2550	\$2.15	\$2.05	\$0.10	4.88%	\$24,214.60
J9001	\$356.35	\$356.13	\$0.22	0.06%	\$24,175.80
J0970	\$29.67	\$28.81	\$0.86	2.99%	\$22,988.66
J9110	\$8.38	\$5.64	\$2.74	48.58%	\$19,253.98
J9250	\$0.20	\$0.17	\$0.03	17.65%	\$18,879.24

A P P E N D I X ~ B

**Table 1: Codes for Which CMS's Reimbursement Amount Exceeded
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Gain to Medicare)
J7192	\$0.92	\$0.91	\$0.01	1.10%	\$18,782.04
Q0166	\$32.54	\$30.80	\$1.74	5.65%	\$17,810.64
J0690	\$0.28	\$0.16	\$0.12	75.00%	\$17,532.00
J9181	\$0.45	\$0.43	\$0.02	4.65%	\$15,624.82
J9070	\$2.34	\$2.27	\$0.07	3.08%	\$14,788.69
J0460	\$0.26	\$0.17	\$0.09	52.94%	\$14,714.28
J9213	\$30.84	\$30.31	\$0.53	1.75%	\$14,446.74
J0670	\$1.60	\$1.49	\$0.11	7.38%	\$14,305.17
J7130	\$1.25	\$0.02	\$1.23	6150.00%	\$13,975.26
J7042	\$0.14	\$0.06	\$0.08	133.33%	\$13,844.48
J9140	\$11.25	\$10.67	\$0.58	5.44%	\$13,735.56
J0595	\$1.82	\$1.22	\$0.60	49.18%	\$13,224.00
90703	\$14.53	\$14.33	\$0.20	1.40%	\$12,742.60
J9091	\$23.43	\$22.69	\$0.74	3.26%	\$12,601.46
J1645	\$9.92	\$9.60	\$0.32	3.33%	\$12,446.08
J0800	\$93.71	\$93.70	\$0.01	0.01%	\$12,271.37
J3315	\$180.93	\$176.24	\$4.69	2.66%	\$11,274.76
J9360	\$0.96	\$0.87	\$0.09	10.34%	\$10,862.55
J2930	\$2.62	\$2.58	\$0.04	1.55%	\$10,626.68
J7030	\$0.10	\$0.08	\$0.02	25.00%	\$10,563.68
J2360	\$15.95	\$15.12	\$0.83	5.49%	\$10,541.00
J9130	\$5.29	\$4.98	\$0.31	6.22%	\$9,850.87
J7040	\$0.05	\$0.04	\$0.01	25.00%	\$8,872.26
J0215	\$26.65	\$26.62	\$0.03	0.11%	\$8,430.90
J9060	\$4.96	\$4.94	\$0.02	0.40%	\$6,431.84
J1390	\$14.83	\$14.41	\$0.42	2.91%	\$6,092.52
J3360	\$0.56	\$0.42	\$0.14	33.33%	\$5,434.10
Q4076	\$0.72	\$0.35	\$0.37	105.71%	\$5,375.36
J9150	\$27.42	\$24.38	\$3.04	12.47%	\$5,192.32
J1610	\$55.17	\$54.65	\$0.52	0.95%	\$2,730.00
J9375	\$7.00	\$6.93	\$0.07	1.01%	\$2,728.25
Q3025	\$85.18	\$85.17	\$0.01	0.01%	\$2,646.79
J9092	\$46.86	\$45.38	\$1.48	3.26%	\$2,641.80
J0637	\$31.88	\$31.79	\$0.09	0.28%	\$2,641.23
J3265	\$2.28	\$2.00	\$0.28	14.00%	\$2,586.36
J1190	\$211.38	\$211.07	\$0.31	0.15%	\$2,553.47
J9080	\$4.69	\$4.54	\$0.15	3.30%	\$2,511.45
J2510	\$8.28	\$8.02	\$0.26	3.24%	\$2,452.58
Q0168	\$8.31	\$8.17	\$0.14	1.71%	\$2,396.66
J1470	\$20.00	\$18.91	\$1.09	5.76%	\$2,389.28
J9017	\$33.30	\$33.29	\$0.01	0.03%	\$2,339.49
J2400	\$16.52	\$16.26	\$0.26	1.60%	\$2,245.36
J1560	\$100.02	\$94.54	\$5.48	5.80%	\$2,076.92
J2540	\$1.00	\$0.54	\$0.46	85.19%	\$2,018.94

A P P E N D I X ~ B

**Table 1: Codes for Which CMS's Reimbursement Amount Exceeded
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Gain to Medicare)
J9370	\$3.50	\$3.47	\$0.03	0.86%	\$2,014.14
90632	\$44.43	\$42.98	\$1.45	3.37%	\$1,771.90
J2354	\$4.67	\$4.61	\$0.06	1.30%	\$1,770.66
J0692	\$6.89	\$6.87	\$0.02	0.29%	\$1,682.20
J1490	\$40.01	\$37.82	\$2.19	5.79%	\$1,600.89
J1500	\$50.01	\$47.28	\$2.73	5.77%	\$1,490.58
J0270	\$1.82	\$1.22	\$0.60	49.18%	\$1,281.60
J0697	\$4.35	\$4.22	\$0.13	3.08%	\$1,248.13
J0610	\$0.05	\$0.04	\$0.01	25.00%	\$1,243.90
J0500	\$13.03	\$12.70	\$0.33	2.60%	\$1,220.01
J0694	\$11.90	\$11.64	\$0.26	2.23%	\$1,193.14
J0170	\$0.29	\$0.27	\$0.02	7.41%	\$1,158.54
90718	\$9.25	\$9.24	\$0.01	0.11%	\$1,107.64
J1160	\$3.04	\$1.51	\$1.53	101.32%	\$962.37
J1956	\$7.64	\$7.61	\$0.03	0.39%	\$879.75
J3105	\$12.66	\$12.40	\$0.26	2.10%	\$812.76
J7120	\$0.76	\$0.75	\$0.01	1.33%	\$776.54
J0743	\$11.72	\$11.64	\$0.08	0.69%	\$776.48
J2765	\$0.45	\$0.43	\$0.02	4.65%	\$757.36
J2680	\$1.14	\$1.13	\$0.01	0.88%	\$716.92
J2700	\$1.61	\$1.57	\$0.04	2.55%	\$662.08
J2020	\$23.76	\$23.68	\$0.08	0.34%	\$499.04
J2810	\$0.38	\$0.30	\$0.08	26.67%	\$495.60
J1720	\$1.81	\$1.80	\$0.01	0.56%	\$450.14
J0295	\$6.67	\$6.61	\$0.06	0.91%	\$438.24
J0290	\$0.21	\$0.20	\$0.01	5.00%	\$427.37
J1600	\$11.30	\$11.28	\$0.02	0.18%	\$378.92
J1460	\$10.00	\$9.46	\$0.54	5.71%	\$331.56
J1480	\$30.00	\$28.37	\$1.63	5.75%	\$324.37
J0540	\$23.02	\$23.01	\$0.01	0.04%	\$245.49
J1530	\$80.02	\$75.63	\$4.39	5.80%	\$237.06
J0744	\$8.57	\$8.47	\$0.10	1.18%	\$224.80
J0282	\$0.38	\$0.28	\$0.10	35.71%	\$219.40
J1455	\$10.63	\$10.62	\$0.01	0.09%	\$213.90
J1327	\$12.40	\$11.90	\$0.50	4.20%	\$184.00
J1510	\$60.05	\$56.73	\$3.32	5.85%	\$169.32
J3230	\$2.39	\$2.22	\$0.17	7.66%	\$151.64
J2795	\$0.08	\$0.07	\$0.01	14.29%	\$148.49
J9218	\$13.49	\$13.15	\$0.34	2.59%	\$146.54
J2560	\$3.17	\$2.52	\$0.65	25.79%	\$101.40
J8530	\$1.02	\$1.00	\$0.02	2.00%	\$99.72
90375	\$62.06	\$61.86	\$0.20	0.32%	\$91.00
J2993	\$877.12	\$873.92	\$3.20	0.37%	\$70.40
J1540	\$90.08	\$85.12	\$4.96	5.83%	\$59.52

A P P E N D I X ~ B

**Table 1: Codes for Which CMS's Reimbursement Amount Exceeded
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Gain to Medicare)
J1815	\$0.22	\$0.21	\$0.01	4.76%	\$41.47
J1165	\$0.61	\$0.54	\$0.07	12.96%	\$39.13
J9380	\$17.50	\$17.34	\$0.16	0.92%	\$38.72
J1955	\$14.65	\$14.10	\$0.55	3.90%	\$30.80
J1520	\$69.96	\$66.14	\$3.82	5.78%	\$30.56
J0456	\$23.56	\$23.55	\$0.01	0.04%	\$26.78
Q0163	\$0.03	\$0.02	\$0.01	50.00%	\$17.80
Q2009	\$5.10	\$4.67	\$0.43	9.21%	\$17.63
J0745	\$0.49	\$0.45	\$0.04	8.89%	\$16.36
J8700	\$7.17	\$7.16	\$0.01	0.14%	\$14.25
J2280	\$3.77	\$3.76	\$0.01	0.27%	\$13.60
J2515	\$1.85	\$1.73	\$0.12	6.94%	\$11.64
J0330	\$0.10	\$0.08	\$0.02	25.00%	\$9.08
Q0178	\$0.08	\$0.07	\$0.01	14.29%	\$7.85
Q0164	\$0.06	\$0.05	\$0.01	20.00%	\$7.14
J2710	\$0.06	\$0.03	\$0.03	100.00%	\$6.87
J8610	\$0.21	\$0.19	\$0.02	10.53%	\$5.08
90633	\$21.95	\$21.42	\$0.53	2.47%	\$4.77
J0706	\$3.27	\$3.26	\$0.01	0.31%	\$3.97
J0360	\$7.13	\$7.12	\$0.01	0.14%	\$3.24
90385	\$25.77	\$25.47	\$0.30	1.18%	\$2.10
J0300	\$2.47	\$2.44	\$0.03	1.23%	\$0.90
J0470	\$18.62	\$18.61	\$0.01	0.05%	\$0.88
J3030	\$49.03	\$49.00	\$0.03	0.06%	\$0.12
Q0172	\$0.09	\$0.08	\$0.01	12.50%	\$0.12
J2940	\$40.16	\$40.15	\$0.01	0.02%	\$0.01
90705	\$13.68	\$13.67	\$0.01	0.07%	\$0.00
90707	\$35.96	\$35.94	\$0.02	0.06%	\$0.00
90716	\$63.23	\$62.41	\$0.82	1.31%	\$0.00
J2941	\$42.38	\$42.32	\$0.06	0.14%	\$0.00
J7344	\$59.63	\$17.68	\$41.95	237.27%	\$0.00
J7613	\$0.07	\$0.05	\$0.02	40.00%	\$0.00
J7614	\$1.28	\$1.09	\$0.19	17.43%	\$0.00
J7616	\$2.60	\$2.50	\$0.10	4.00%	\$0.00
J9035	\$57.08	\$57.07	\$0.01	0.02%	\$0.00
J9305	\$40.54	\$40.53	\$0.01	0.02%	\$0.00
Q2019	\$1,476.21	\$1,468.31	\$7.90	0.54%	\$0.00
J3246	\$7.85	\$7.77	\$0.08	1.03%	Not Available
Total					\$115,221,345.93

► A P P E N D I X ~ C

**Table 2: Codes for Which CMS's Reimbursement Amount Was Less Than
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Loss to Medicare)
J2430	\$59.06	\$62.15	-\$3.09	-4.97%	-\$1,633,151.52
J9170	\$297.58	\$298.75	-\$1.17	-0.39%	-\$1,014,778.44
J0696	\$6.57	\$6.76	-\$0.19	-2.81%	-\$435,180.94
J7517	\$2.51	\$2.52	-\$0.01	-0.40%	-\$422,437.93
J9350	\$739.69	\$744.25	-\$4.56	-0.61%	-\$280,996.32
J7502	\$3.90	\$3.94	-\$0.04	-1.02%	-\$257,177.92
J7631	\$0.10	\$0.12	-\$0.02	-16.67%	-\$173,850.20
J0585	\$4.71	\$4.72	-\$0.01	-0.21%	-\$126,373.93
J9206	\$125.58	\$125.64	-\$0.06	-0.05%	-\$64,532.58
J2405	\$3.73	\$3.74	-\$0.01	-0.27%	-\$46,285.91
J9310	\$442.01	\$442.03	-\$0.02	0.00%	-\$27,610.78
J9209	\$16.69	\$16.90	-\$0.21	-1.24%	-\$26,215.14
J9208	\$62.04	\$62.91	-\$0.87	-1.38%	-\$23,229.87
J2788	\$24.47	\$24.97	-\$0.50	-2.00%	-\$23,170.50
J1450	\$44.85	\$49.11	-\$4.26	-8.67%	-\$23,110.50
J2780	\$0.93	\$1.00	-\$0.07	-7.00%	-\$20,904.03
J1650	\$5.15	\$5.19	-\$0.04	-0.77%	-\$18,403.48
J0702	\$4.51	\$4.52	-\$0.01	-0.22%	-\$9,725.23
J1750	\$11.06	\$11.07	-\$0.01	-0.09%	-\$8,312.74
J9040	\$55.01	\$55.67	-\$0.66	-1.19%	-\$8,300.16
J1440	\$178.94	\$178.95	-\$0.01	-0.01%	-\$6,536.72
J9211	\$317.27	\$322.72	-\$5.45	-1.69%	-\$5,847.85
J1630	\$2.56	\$3.07	-\$0.51	-16.61%	-\$5,755.35
J1110	\$28.75	\$29.88	-\$1.13	-3.78%	-\$4,680.46
J2001	\$0.01	\$0.02	-\$0.01	-50.00%	-\$2,641.37
J0780	\$3.01	\$3.20	-\$0.19	-5.94%	-\$2,369.87
J9340	\$43.57	\$43.79	-\$0.22	-0.50%	-\$1,818.08
J9293	\$321.80	\$321.82	-\$0.02	-0.01%	-\$1,694.00
J3260	\$1.98	\$2.00	-\$0.02	-1.00%	-\$1,234.42
J1070	\$4.91	\$4.92	-\$0.01	-0.20%	-\$1,123.93
J7682	\$46.98	\$46.99	-\$0.01	-0.02%	-\$906.43
J2543	\$4.59	\$4.65	-\$0.06	-1.29%	-\$881.22
J7509	\$0.07	\$0.08	-\$0.01	-12.50%	-\$874.54
J1230	\$3.28	\$3.29	-\$0.01	-0.30%	-\$344.39
J1590	\$0.44	\$0.45	-\$0.01	-2.22%	-\$254.53
J1051	\$4.89	\$4.90	-\$0.01	-0.20%	-\$221.16
J2440	\$0.76	\$0.84	-\$0.08	-9.52%	-\$178.56
J1790	\$1.02	\$1.13	-\$0.11	-9.73%	-\$171.71

A P P E N D I X ~ C

**Table 2: Codes for Which CMS's Reimbursement Amount Was Less Than
OIG's Reimbursement Amount**

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount	Difference Between CMS and OIG	% Difference Between CMS and OIG	Estimated Monetary Impact of Correcting CMS's Calculation (Loss to Medicare)
90371	\$113.57	\$113.94	-\$0.37	-0.32%	-\$167.24
J2370	\$0.63	\$0.75	-\$0.12	-16.00%	-\$111.48
J2185	\$3.40	\$3.41	-\$0.01	-0.29%	-\$101.18
J0715	\$2.70	\$2.73	-\$0.03	-1.10%	-\$95.70
J0725	\$2.58	\$2.59	-\$0.01	-0.39%	-\$71.63
J2320	\$3.41	\$3.43	-\$0.02	-0.58%	-\$47.96
J9098	\$350.45	\$350.46	-\$0.01	0.00%	-\$27.69
J1800	\$5.10	\$5.11	-\$0.01	-0.20%	-\$16.58
J3305	\$136.93	\$136.94	-\$0.01	-0.01%	-\$10.44
J1180	\$4.00	\$4.01	-\$0.01	-0.25%	-\$10.21
90376	\$66.31	\$66.36	-\$0.05	-0.08%	-\$6.95
J0720	\$6.10	\$6.11	-\$0.01	-0.16%	-\$5.57
90700	\$12.81	\$12.96	-\$0.15	-1.16%	-\$2.40
J2783	\$107.01	\$107.02	-\$0.01	-0.01%	-\$2.26
Q2017	\$263.67	\$265.15	-\$1.48	-0.56%	-\$1.48
J7110	\$10.71	\$10.72	-\$0.01	-0.09%	-\$0.72
90585	\$122.54	\$122.55	-\$0.01	-0.01%	-\$0.10
Q2007	\$63.36	\$63.37	-\$0.01	-0.02%	-\$0.02
90396	\$109.82	\$109.83	-\$0.01	-0.01%	-\$0.01
J0180	\$121.12	\$121.14	-\$0.02	-0.02%	\$0.00
J7518	\$2.42	\$2.43	-\$0.01	-0.41%	\$0.00
Q0171	\$0.10	\$0.11	-\$0.01	-9.09%	\$0.00
Q0176	\$0.26	\$0.27	-\$0.01	-3.70%	\$0.00
Total					-\$4,681,962.33

► A P P E N D I X ~ D

Table 3: Codes for Which CMS's Reimbursement Amount and OIG's Reimbursement Amount Were the Same

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount
Q2014	\$8.77	\$8.77
J2505	\$2,273.93	\$2,273.93
J3487	\$198.39	\$198.39
J9263	\$8.24	\$8.24
J9201	\$115.34	\$115.34
J7626	\$4.03	\$4.03
J9219	\$2,206.27	\$2,206.27
J7320	\$200.15	\$200.15
J9355	\$52.99	\$52.99
J1441	\$282.41	\$282.41
Q0137	\$3.54	\$3.54
J2792	\$13.40	\$13.40
J7190	\$0.52	\$0.52
J9395	\$80.51	\$80.51
J9185	\$272.09	\$272.09
J7520	\$6.73	\$6.73
J1785	\$3.91	\$3.91
Q4077	\$54.02	\$54.02
J9031	\$118.41	\$118.41
J0207	\$417.56	\$417.56
J7515	\$0.99	\$0.99
J7198	\$1.09	\$1.09
J2324	\$73.33	\$73.33
J7195	\$0.84	\$0.84
J9010	\$511.48	\$511.48
J7193	\$0.75	\$0.75
J9015	\$672.06	\$672.06
J9178	\$25.41	\$25.41
J7050	\$0.02	\$0.02
Q4054	\$3.54	\$3.54
J9160	\$1,205.53	\$1,205.53
J9291	\$141.14	\$141.14
J0587	\$7.76	\$7.76
Q2022	\$0.72	\$0.72
J9268	\$1,870.88	\$1,870.88
J9290	\$65.91	\$65.91
J1756	\$0.36	\$0.36
J7342	\$15.32	\$15.32
J9096	\$6.04	\$6.04
J7500	\$0.19	\$0.19
J9300	\$2,203.67	\$2,203.67

A P P E N D I X - D

Table 3: Codes for Which CMS's Reimbursement Amount and OIG's Reimbursement Amount Were the Same

HCPCS Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount
J9093	\$0.60	\$0.60
J2916	\$4.83	\$4.83
J9065	\$43.29	\$43.29
J7639	\$16.93	\$16.93
J9095	\$3.02	\$3.02
J3240	\$699.60	\$699.60
J8521	\$10.76	\$10.76
J0287	\$11.94	\$11.94
J1020	\$2.67	\$2.67
J7340	\$26.51	\$26.51
J1335	\$21.30	\$21.30
J0289	\$20.38	\$20.38
J1212	\$36.79	\$36.79
J9280	\$23.38	\$23.38
J3130	\$14.99	\$14.99
J9200	\$71.39	\$71.39
J7308	\$87.65	\$87.65
J1655	\$2.60	\$2.60
J0205	\$39.22	\$39.22
J0600	\$39.74	\$39.74
J1670	\$68.47	\$68.47
J0285	\$29.84	\$29.84
J1570	\$33.93	\$33.93
J9050	\$139.10	\$139.10
J9097	\$12.08	\$12.08
J9094	\$1.21	\$1.21
J1410	\$56.71	\$56.71
J9320	\$153.82	\$153.82
J0550	\$29.91	\$29.91
J0570	\$30.41	\$30.41
J0740	\$762.50	\$762.50
J0713	\$3.74	\$3.74
J9600	\$2,285.15	\$2,285.15
J7194	\$0.49	\$0.49
J9245	\$388.73	\$388.73
J0476	\$67.55	\$67.55
90586	\$118.41	\$118.41
J2920	\$1.92	\$1.92
J1000	\$5.02	\$5.02
90675	\$115.02	\$115.02
Q4075	\$0.03	\$0.03
J0850	\$672.61	\$672.61

A P P E N D I X ~ D

Table 3: Codes for Which CMS's Reimbursement Amount and OIG's Reimbursement Amount Were the Same

HCPDS Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount
J3120	\$7.49	\$7.49
J0580	\$60.28	\$60.28
J7513	\$380.28	\$380.28
J3475	\$0.01	\$0.01
J0530	\$11.37	\$11.37
J3465	\$4.55	\$4.55
J2760	\$22.47	\$22.47
J2322	\$13.86	\$13.86
Q0167	\$4.00	\$4.00
J2545	\$39.05	\$39.05
J2770	\$103.25	\$103.25
J7511	\$297.78	\$297.78
J9020	\$54.52	\$54.52
J1438	\$147.16	\$147.16
J0560	\$17.29	\$17.29
J3415	\$2.36	\$2.36
J2597	\$2.47	\$2.47
J0770	\$45.09	\$45.09
J0760	\$4.07	\$4.07
J7525	\$124.27	\$124.27
J3320	\$28.65	\$28.65
Q0165	\$0.04	\$0.04
J3250	\$4.12	\$4.12
J9266	\$1,459.51	\$1,459.51
J2321	\$6.56	\$6.56
J9230	\$10.45	\$10.45
J2501	\$4.02	\$4.02
J0130	\$431.24	\$431.24
J3100	\$2,040.05	\$2,040.05
J1980	\$4.71	\$4.71
J1652	\$6.74	\$6.74
J1270	\$2.80	\$2.80
J2730	\$85.79	\$85.79
J1120	\$12.70	\$12.70
J8520	\$3.24	\$3.24
J9151	\$55.99	\$55.99
J9120	\$12.07	\$12.07
J7100	\$14.05	\$14.05
J0630	\$35.03	\$35.03
J0592	\$0.82	\$0.82
J7501	\$46.88	\$46.88
J1380	\$11.36	\$11.36

A P P E N D I X ~ D

Table 3: Codes for Which CMS's Reimbursement Amount and OIG's Reimbursement Amount Were the Same

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount
J2675	\$1.93	\$1.93
J0636	\$0.71	\$0.71
J7504	\$283.59	\$283.59
J0210	\$9.03	\$9.03
J7330	\$16,284.90	\$16,284.90
J2690	\$0.90	\$0.90
J0515	\$3.40	\$3.40
J1835	\$36.23	\$36.23
J7516	\$20.59	\$20.59
J3364	\$8.15	\$8.15
J3365	\$407.54	\$407.54
J3486	\$18.74	\$18.74
J3411	\$0.58	\$0.58
J7310	\$4,240.00	\$4,240.00
J0583	\$0.15	\$0.15
J1742	\$223.65	\$223.65
J1840	\$0.23	\$0.23
J7505	\$830.01	\$830.01
J2995	\$76.32	\$76.32
J1240	\$4.73	\$4.73
J1830	\$80.53	\$80.53
J1364	\$2.94	\$2.94
J2410	\$2.29	\$2.29
J3485	\$0.96	\$0.96
J1320	\$1.79	\$1.79
J1730	\$112.01	\$112.01
Q2012	\$154.05	\$154.05
J8560	\$31.03	\$31.03
J2210	\$4.30	\$4.30
J2590	\$1.04	\$1.04
J1595	\$34.85	\$34.85
J0275	\$20.75	\$20.75
Q2002	\$2.98	\$2.98
Q0177	\$0.07	\$0.07
J1205	\$9.13	\$9.13
Q0170	\$0.16	\$0.16
Q0169	\$0.28	\$0.28
Q2021	\$133.75	\$133.75
Q2006	\$555.03	\$555.03
J2720	\$0.36	\$0.36
Q0175	\$0.21	\$0.21
90704	\$17.81	\$17.81

A P P E N D I X ~ D

Table 3: Codes for Which CMS's Reimbursement Amount and OIG's Reimbursement Amount Were the Same

HCPSC Code	CMS's Reimbursement Amount	OIG's Reimbursement Amount
90706	\$14.98	\$14.98
J0128	\$68.62	\$68.62
J0135	\$577.56	\$577.56
J0878	\$0.28	\$0.28
J2357	\$15.32	\$15.32
J2469	\$18.22	\$18.22
J2794	\$4.60	\$4.60
J3396	\$8.99	\$8.99
J7611	\$0.07	\$0.07
J7612	\$0.87	\$0.87
J8501	\$4.62	\$4.62
J8510	\$1.91	\$1.91
J9041	\$28.38	\$28.38
J9055	\$49.64	\$49.64
J1457	\$1.25	\$1.25
J1931	\$22.74	\$22.74
J7674	\$0.41	\$0.41
Q2003	\$2.15	\$2.15
Q2008	\$11.55	\$11.55

➤ **A P P E N D I X ~ E**

Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 22 2005

TO: Daniel R. Levinson
Inspector General
Office of Inspector General

FROM: Mark B. McClellan, M.D., PhD *MM*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General's Draft Report: "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs." We appreciate the OIG's commitment to ensuring appropriate payments and identifying opportunities for improvement to the average sales price (ASP) methodology. The report's findings are helpful to our ongoing refinement of the ASP payment methodology.

The OIG report examines the ASP calculation and recommends an alternative formula be used to establish the payment amounts. Using the OIG's recommended alternative calculation, the report estimates payments would decrease for a number of drugs, while the payment for certain other drugs would increase. The report also notes that differences in the ASP calculation affect the monitoring of the ASPs and potential adjustments of the prices.

We continue to work toward refinements in the ASP payment methodology, and are already addressing the subject matter of this OIG report. In August, we presented the current ASP formula in the 2006 Physician Fee Schedule (PFS) proposed rule 70 Fed. Reg. 45764, 45844 (Aug. 8, 2005), and received public comments on our approach. We indicated in the 2006 PFS final rule 70 Fed. Reg. 70116, 70218 (Nov. 21, 2005) that, as we gain more experience with the ASP data and other sources of information become available, we may consider altering the methodology or establishing exceptions as suggested in some of the public comments. CMS is in the process of implementing the ASP methodology as set forth in the regulations, prices appear to be stabilizing and emerging reports indicate that overall, beneficiaries' access to care has been maintained during the transition to generally lower drug payments.

We thank the OIG for their work on this report and will consider the information it contains in our ongoing efforts to enhance implementation of the new ASP payment methodology.

► A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Lauren McNulty, *Team Leader*

Linda Boone Abbott, *Program Specialist*